

K113153

NOV 28 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: K113153.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD

Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

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Contact Person:

Tan Chuanbin

Shenzhen Mindray Bio-medical Electronics Co., LTD

Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: October 10th, 2011

2. Device Name:

DP-20 Digital Ultrasonic Diagnostic Imaging System (new added sub-model)

DP-30 Digital Ultrasonic Diagnostic Imaging System (new added sub-model)

Classification

Regulatory Class: II

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System are general purpose, portable/mobile (with mobile ultrasound trolley), software controlled, ultrasonic diagnostic systems. Its function is to acquire and display ultrasound data in B-Mode,

M-Mode, or their combined mode B+M Mode. The systems are Track 1 device that employs an array of transducers including linear array and convex array. The frequency range of DP-20 is approximately 2.0 MHz to 10.0 MHz and that of DP-30 is approximately 2.0 MHz to 12.0 MHz.

4. Intended Use:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intraoperative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vascular and urology exams.

5. Comparison with Predicate Device:

DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is comparable with and substantially equivalent to the Mindray DP-6900 Digital Ultrasonic Diagnostic Imaging System (K090912), M5 Diagnostic Ultrasound System(K102991) and M7 Diagnostic Ultrasound System(K103677). They have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate device.

6. Non-clinical Tests:

DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: UD 2, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37, IEC 60601-1-4, ISO 10993-1 and IEC 62304.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent with respect to safety and effectiveness to devices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

DEC - 6 2011

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd, Suite 200
GREAT NECK NY 11021

Re: K113153

Trade/Device Name: DP-20, DP-30 Digital Ultrasonic Diagnostic Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: October 10, 2011
Received: October 25, 2011

Dear Ms. Goldstein-Falk:

This letter corrects our substantially equivalent letter of November 28, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DP-20, DP-30 Digital Ultrasonic Diagnostic Imaging System, as described in your premarket notification:

Transducer Model Number

35C20EA
35C50EB
65C15EA

65EC10EB
65EL60EA
75L38EB

75L53EA
75LT38EA
35C20EA

35C50EA
65C15EA
65EC10EA
65EL60EA

65EB10EA
65EC10ED
75L38EA
75L53EA

75LT38EA
10L24EA

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K 613153

Device Name: DP-20, DP-30 Digital Ultrasonic Diagnostic Imaging System

Indications for Use:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intraoperative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vascular and urology.

Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Michael D. Kline
Division Director
Division of Biologics
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K 613153

0029

Diagnostic Ultrasound Indications for Use Form

System Transducer
 Model: DP-20
 510(k) Number(s) K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N					N	Note 1, Note 2
Abdominal	N	N					N	Note 1, Note 2
Intraoperative (specify)*	N	N					N	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N					N	Note 1, Note 2
Small organ (specify)**	N	N					N	Note 2
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic	N	N					N	Note 2
Trans-rectal	N	N					N	Note 2
Trans-vaginal	N	N					N	Note 2
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-Skeletal Conventional	N	N					N	Note 1, Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult	N	N					N	Note 2
Cardiac Pediatric	N	N					N	Note 2
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Operative								
Peripheral Vascular	N	N					N	Note 2
Other (specify)***	N	N					N	Note 1, Note 2

N=new indication, P=previously cleared by FDA, E=added under Appendix E

Additional columns: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The system does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrent of CDER, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR
801.109)


 Division Sign-Off
 Division of Radiological Devices
 Office of In Vitro Diagnostic Devices Evaluation and Safety

510(k) K113153

0030

NOV. 29. 2011 1:44PM

NU. 1241 F. 3716

Diagnostic Ultrasound Indications for Use Form
 System _____ Transducer _____
 Model: 35C20EA
 510(k) Number(s) 6113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amp/Phase Doppler	Combined (specify)	Other (specify)
Orthopaedic								
Pelvic								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-rectal								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	P	P					P	Note 2
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Tumor-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

New use indication: P=previously cleared by FDA; E=added under Appendix E

Additional comment: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: These Mammographic Imaging. The fixture does not use coherent imaging.

Note 2: Biopsy Guidance

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Concurrent use of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Susan D. Goldstein
 (Susan D. Goldstein
 Director of Radiological Devices
 Office of Medical Device Evaluation and Safety
 Center for Devices and Radiological Health)

SICK 6113153

0031

NOV. 29. 2011 1:44PM

FD-1441 F. 0/24

Diagnostic Ultrasound Indications for Use Form

System

Transducer

x

Model:

35C50EB

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Orthopaedic								
Fetal	N	N					N	Note 1, Note 2
Abdominal	N	N					N	Note 1, Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N					N	Note 1, Note 2
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (inc-Card)								
Musculo-skeletal							N	Note 1, Note 2
Conventional	N	N						
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular							N	Note 1, Note 2
Other (specify)**	N	N						

N= new indication; P= previously cleared by FDA; B= added under Appendix B

Additional columns: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ= liver, thyroid, testes.

***Other use includes Urology.

Note 1: Trans-Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance.

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Concurrent use of CDRH, Office of Device Evaluation (ODE)

Prescription USE (For 21 CFR
801.109)Michael D. O'Dell
Division Manager
Division of Diagnostic Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

STK: K113153

0032

NOV. 29. 2011 1:44PM

NW 1441 R 0/44

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

65EC10FB

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Temi	N	N					N	Note 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Nonop)								
Laparoscopic								
Pediatric								
Small organ (specify)**								
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic								
Trans-rectal	N	N					N	Note 2
Trans-vaginal	N	N					N	Note 2
Trans-urethral								
Trans-cervix (non-Cord.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intramuscular (Cordic)								
Trans-cervix (Cardiac)								
Intra-Cordic								
Peripheral Vascular							N	Note 2
Other (specify)***	N	N						

*New indication; **Previously cleared by FDA; ***Added under Appendix B

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ intact, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The device does not use contrast agents.

Note 2: Clotolytic Guidance

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Centers for Devices and Radiological Health, Office of Devices Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)



 (Signature Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K113153

0034

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Diagnostic Ultrasound Indications for Use Form

Transducer *

System

Model:

510(k) Number(s)

6SEL616A

K11315

Clinical Application	Mode of Operation							Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(s) (specify)**								
Normal Cephalic								
Adult Cephalic								
Trans-rectal	P	P					P	Note 2
Trans-vaginal								
Trans-gastric								
Trans-esoph. (non-Card.)								
Musculoskeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Cardiac								
Peripheral Vascular							P	Note 2
Other (specify)***	P	P						

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ: breast, thyroid, testes.

***Other can include Urology.

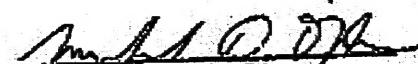
Note 1: Tissue Harmonic Imaging: The scanner does not use contrast agents.

Note 2: Biopsy Guidance

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Comments of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)



 (Device Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

S10K K113153

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Diagnostic Ultrasound Indications for Use Form

System

Model:

510(k) Number(s)

7513465

Transducer

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N					N	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N					N	Note 2
Small organ (specify)**	N	N					N	Note 2
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic								
Trans-abdominal								
Trans-vaginal								
Trans-rectal								
Trans-esophageal (Card.)								
Musculo-skeletal Conventional	N	N					N	Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intraocular (Ocular)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Pediatric Vascular	N	N					N	Note 2
Other (specify)***								

N=New indication; P=previously claimed by FDA; C=adding under Appendix B

Additional exam modes: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ=breast, thyroid, testes.

***Other use includes Urology.

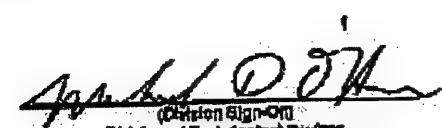
Note 1: Tissue Harmonic Imaging. The fixture does not use contrast agents.

Note 2: Biopsy Guidance

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CE Clearance of CDER, Office of Device Evaluation(ODE)

Prescription UKB (Per 21 CFR 801.109)



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K113153

0036

Diagnostic Ultrasound Indications for Use Form

System:
Model:
SIC(k) Number(s)

75153EA

K8/3157

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Endoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intraocular								
Cardiac, Adult								
Cardiac, Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

New use indication: P- previously cleared by FDA; B- added under Appendix B

Additional comment: Combined modes: B+P

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ means, thyroid, liver, etc.

***Other use includes Urology.

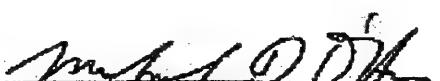
Note 1: Tissue Harmonic Imaging. This feature does not use combined systems.

Note 2: Biopsy Guidance

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Conurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)



Michael D. O'Dell
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

DIN: K (315)

0037

Diagnostic Ultrasound Indications for Use Form
 System TSLT3RDA Transducer
 Model S10(k) Number(s) K13153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude-Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Pelvic								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*	P	P					P	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cardiac	P	P					P	Note 2
Adult Cardiac								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Venous	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously claimed by FDA; B=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-brain, thyroid, testes.

***Other use includes Urology.

Note 1: Trans-Esophageal Imaging. The scanner does not use contrast agents.

Note 2: Biopsy Guidance

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Comments to CDRH, Office of Devices Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)


 (Signature Sign-off)

Division of Radiological Devices
 Office of In Vitro Diagnostic Devices, Evaluation and Safety

610K K13153

0038

NOV. 29, 2011 1:53PM

NO. 124 / P. 13/24

Diagnostic Ultrasound Indications for Use Form

System

Indications

Model:

DP-50

510(k) Number(s)

K13153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Ampibiole Doppler	Combined (specify)	Other (specify)
Orthopaedic								
Reint.	N	N					N	Note 1, Note 2
Abdominal	N	N					N	Note 1, Note 2
Intraoperative (specify)*	N	N						
Intraoperative (Neuro)								
Laparoscopy								
Pediatric	N	N					N	Note 1, Note 2
Small organs (specify)**	N	N					N	Note 2
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic	N	N					N	Note 2
Trans-rectal	N	N					N	Note 2
Trans-vaginal	N	N						
Trans-uterine								
Trans-cereph (non-Card.)								
Musculo-skeletal	N	N					N	Note 1, Note 2
Conventional							N	Note 2
Musculo-skeletal Superficial	N	N						
Intra-muscular							N	Note 2
Cardiac Adult	N	N					N	Note 2
Cardiac Pediatric	N	N					N	Note 2
Intra-vascular (Cardiac)								
Trans-cereph (Cardiac)								
Intra-Cardiac								
Peripheral vascular	N	N					N	Note 1, Note 2
Other (specify)***	N	N					N	Note 1, Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organs-breed, thyroid, testes.

***Other uses includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Conurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR
801.109)


 (Signature) Susan B. Goldstein-Falk
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

910K K13153

0039

NOV. 29. 2011 1:53PM

NO. 1247 P. 14/24

Diagnostic Ultrasound Indications for Use Form

System:

Transducer

X

Model:

35C706A

510(k) Number(s)

K113157

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Orthopedic								
Fetal								
Abdominal	P	Z					P	Note 2
Intraoperative (specify)*								
Intraoperative (None)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(s)***								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-rectal								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	P	P					P	Note 2
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-cereph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=novel indication; P=previously cleared by FDA; E=added under Appendix B

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breed, thyroid, testes.

***Other use includes Urology.

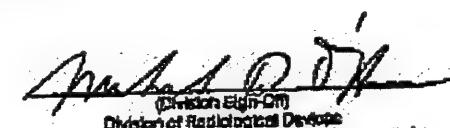
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrent use of CDER, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)



Division Sign-On
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K113157

0040

NOV. 29, 2011 1:53PM

NU. 141 P. 10/14

Diagnostic Ultrasound Indications for Use Form

System

Model:

510(k) Number(s)

Transducer

35C50RA

k113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P					P	Note 1, Note 2
Abdominal	P	P					P	Note 1, Note 2
Intraoperative (specify)*								
Intraoperative (Note)								
Laparoscopic								
Pediatric	P	P					P	Note 1, Note 2
Small organ(s) (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-cervix (non-Card.)								
Musculo-skeletal	P	P					P	Note 1, Note 2
Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-coupl. (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P					P	Note 1, Note 2

N=new indication; P=previously cleared by FDA; Bolded under Appendix E.

Additional components: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrents of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR
801.109)

Susan S. Goldstein-Falk
 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K k113153

0041

NOV. 29, 2011 1:59PM

NU. 1241 2. 10/24

Diagnostic Ultrasound Indications for Use Form
TransducerSystem: 65C15EA
Model: 510(k) Number(s) 510/3153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Pain								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 1
Small organ (specify)**							P	Note 2
Neonatal Cephalic	P	P					P	Note 3
Adult Cephalic	P	P						
Trans-rectal								
Trans-vaginal								
Transcardial								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric	P	P					P	Note 2
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

New Indication: P=previously cleared by FDA, E=added under Appendix E

Additional comment: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

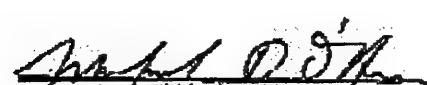
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrent of CDER, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 803.109)



 Division Engg-CM
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety
610K 510/3153

0042

NOV. 29, 2011 1:59PM

NU. 1241 P. 11/14

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

65PC10EA

510(k) Number(s)

K. 113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Absolutive Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P					P	Note 2
Abdominal								
Intraoperative (specify)*								
Intracardiac (Neuro)								
Laparoscopic								
Pediatric								
Small organ (specify)**								
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-sternal	P	P					P	Note 2
Trans-vaginal	P	P					P	Note 2
Trans-urethral								
Trans-cereph (non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-cereph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular							P	Note 2
Other (specify)***	P	P						

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional constraint: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

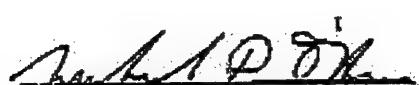
Note 1: Tissue Harmonic Imaging. The device does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrents of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)



(Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K 113153

0043

NOV. 29 2011 1:59PM

REC. 1/47 P. 10/24

Diagnostic Ultrasound Indications for Use Form

System: _____
 Model: 65BL60CA
 510(k) Number(s): 6113153

Clinical Application	Mode of Operation							Other (specify)
	B	M	PWD	CWD	Color Doppler	Amp/Blnd Doppler	Combined (specify)	
Orthopaedic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Transrectal	P	P					P	Note 2
Trans-vaginal								
Trans-oesophageal								
Trans-cervical (non-Cerv.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P					P	Note 2

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional comments: Combined under: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ breast, thyroid, testes.

***Other use includes Urology.

Note 1: Ultrasound Hemodynamic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrent of CDERH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

Susan D. Goldstein
 Division Engg-Off
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

SINCE K113153

0044

NOV. 29, 2011 1:59PM

RU. 1251 R. 1374

Diagnostic Ultrasound Indications for Use Form

System: _____ Transducer: _____
 Model: 4TEB105A
 510(k) Number(s): K13153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Name)								
Laparoscopy								
Pediatric								
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N					N	Note 2
Trans-vaginal								
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Cardiac								
Peritoneal Vascular							N	Note 2
Other (specify)***	N	N						

N=new indication; P=previously cleared by FDA; B=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ: breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Comments of CDRH, Office of Devices Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)



(Device Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K13153

0045

NOV. 29, 2011 1:59PM

NU. 1241 F. 2974

Diagnostic Ultrasound Indications for Use Form

System

Model:

510(k) Number(s)

Transducer

N

6SEC10FD

K1013/53

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Orthopaedic								
Fetal	N	N					N	Note 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Endovascular								
Pediatric								
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal	N	N					N	Note 2
Trans-rectal								
Intra-cerebral (non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-cerebral (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***								

N=new Indication; P=previously claimed by FDA; B=added under Appendix E

Additional columns=Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-brain, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. This feature does not use contrast agents.

Note 2: Biopsy Guidance

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Consenttees of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Susan D. Goldstein
 Division Sign-Off
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

SIGN K1013

0046

NOV. 29, 2011 1:59PM

RU 1241 R 11/29

Diagnostic Ultrasound Indications for Use Form

System: _____ Transducer: _____
 Model: 79L38EA S10(k) Number(s): 5103153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Luminescopic								
Podiatric	P	P					P	Note 2
Small organ(s)***	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-anal								
Trans-esoph/ma-Card.								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Tissue-ctophy (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication, P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Etcery Guidance

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Committee of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

Susan D. Goldstein
 (Division 801-00)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K 5103153

0047

NOV. 29, 2011 2:00PM

AU 1241 F 22/67

Diagnostic Ultrasound Indications for Use Form
Transducer

System

Model:

510(k) Number(s)

75L53EA

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Optophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Extraperitoneal (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(s)***	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-cervical (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-cervical (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

*New indication; P=previously cleared by FDA; P=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes circumferential, thoracic, and vascular.

**Small organ-brain, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The device does not use cut-off filter.

Note 2: Bipart Guidance

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Conurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USP (Par 21 CFR 801.109)

Susan O. Goldstein
 Division Sign-Off
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

0048

NOV. 29, 2011 2:00PM

SU 1241 P. 15/16

Diagnostic Ultrasound Indications for Use Form

System _____
 Model: 75LT38RA
 SIRIUS Number(s) K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Orthopaedic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*	P	P					P	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ (specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Carotid								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; B=added under Appendix E

Additional comment: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ=breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Conurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

Susan O. Goldstein
 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

K113153

0049

NOV. 29, 2011 2:00PM

NU. 1241 F. 23/24

Diagnostic Ultrasound Indications for Use Form

System

Model:

510(k) Number(s)

73LT95BA

K11315

Transducer

X

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*	P	P					P	Note 2
Intraoperative (Normal)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ (specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intraventricular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=New Indication; P=Previously cleared by FDA; B=Added under Appendix II

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other uses include Urology.

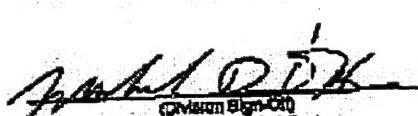
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)



Division Sign-Off
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K11315

0049

NOV. 29, 2011 2:00PM

NU. 124/ F. 24/24

Diagnostic Ultrasound Indications for Use Form
Transducer

System

Model:

510(k) Number(s)

10L24BA

1613153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Orthopaedic								
Pelvic								
Abdominal								
Locoregionative (specify)*								
Intraoperative (Note)								
Laparoscopic								
Pediatric								
Small organ (specify)**	N	N					N	Note 2
Neonatal Cephalic								
Adult Cephalic								
Trans-cervical								
Intra-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	N	N					N	Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N					N	Note 2
Other (specify)***								

N=new Indications Previously cleared by FDA; B=added under Appendix E.

Additional comment: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ breast, thyroid, testes.

***Other uses includes Urology.

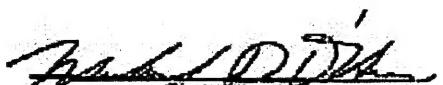
Note 1: Flame Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrent of CDER, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)



 Susan B. Goldstein-Falk
 Director, Diagnostic Imaging
 Division of Medical Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety
STCK K10152

0050

NOV. 29. 2011 2:00PM

NO. 1241 F. 14/14

Diagnostic Ultrasound Indications for Use Form

System

Model

510(k) Number(s)

101-3454

Transducer

x

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ (specify)**	N	N					N	Note 2
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph. (not Card.)								
Musculo-skeletal Conventional	N	N					N	Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N					N	Note 2
Other (specify)***								

N=new indication; E=previously cleared by FDA; B=added under Appendix B
Additional comment: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-bariatric, thyroid, testes

***Other uses include: Urology.

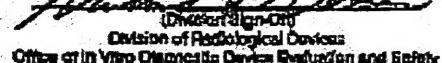
Note 1: Trans Harmonic Imaging. This feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription USB (Per 21 CFR 801.109)


 (Signature)
Division Sign-Off
Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

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